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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,508	03/15/2004	Ricardo Azevedo Pontes De Carvalho	11190-10	3187

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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,508	DE CARVALHO ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *16,17,30-34,41 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 10, 11, 14, 19, 22, 23, 28, 35, 37, 38, 40, 42, 43, 46, 47, 50, 51, 53, 57-59, 61 and 67-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/15/2007; 04/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,10,11,14,16,17,19,22,23,28,30-35,37,38,40-43,46,47,49-51,53,57-59,61 and 67-70.

DETAILED ACTION

Election/Restrictions

Claims 16, 17, 30-34, 41, 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 7, 2008.

Applicant's comments regarding the claims and the species are noted. The examiner has carefully reviewed applicant's election and comments and has withdrawn the above recited claims.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "44" and "49" have both been used to designate the drum in figures 16 and 18.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the valve which connects the first tube to the first cavity (claim 4, figure 19 is insufficient and does not show any valve), reflux mechanism (claim 47) and the valve to prevent overfilling (claim 46), must be shown or the feature(s) canceled from the claim(s). The examiner also cannot locate in the drawings the first and second refill tubes and ports, and first valves, implying a second of each of these. These embodiments are found in most of the

claims. The attachment mechanism for the refill port having the tube (claim 50) is also not found in the drawings. The examiner cannot find a disclosure wherein the drum is secured to the eye by any mechanism.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-6, 10, 11, 14, 19, 22, 23, 28, 35, 37, 38, 40, 42, 43, 46, 47, 50, 51, 53, 57-59, 61 and 67-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 7,195,774 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are directed to the implantable delivery device which provides for unidirectional delivery of a therapeutic agent, particularly to the ocular region. Claim 1 of this application includes the claimed adhesive and dependent claims recite the refill port. Further, nothing prevented applicant from claiming the first tube for filling the refill port as a dependent claim in the parent application.

Claim Objections

Claims 32, 38 and 53 are objected to because of the following informalities: Claim 32 contains two periods, "..". Claim 38 contains the phrase "is comprises", claim 53 contains the phrase "said said". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 14, 23, 37, 38, 46, 47, 50, 68 are rejected under 35 U.S.C. 112, first paragraph.

Regarding claim 23, applicant claims an iontophoretic pump and an osmotic pump in combination with a refillable reservoir. This has not been previously disclosed in combination and the examiner is unable to conceive of a refillable port which would be operable using that pump technology, particularly the osmotic pump technology. Regarding claim 14, applicant claims a septum which may be opaque in imaging techniques. Note is made of applicant's specification, paragraph [0113], however, this disclosure is insufficient. Resealable septums are generally incompatible with radiopaque markers, and applicant's conclusory disclosure is insufficient. Regarding claim 37, applicant has not disclosed an example of a slow release formulation, accordingly, this embodiment is not enabled. Regarding claim 38, applicant claims the various retaining agents such as crossing band, strip, net and flanges. Applicant has not disclosed these structural elements in combination with a refill port, only with use of a tablet. See applicant's specification, [0158]+. "Crossing bands" are new matter, as the term is not disclosed in the original specification. Regarding claim 50, the attachment mechanism to facilitate implantation of the refilling port having the tube does not appear to have been disclosed. The examiner cannot locate a disclosure for attaching drum 49 to the eye. Regarding claim 68, the specification, while being enabling for viscous materials, does not reasonably provide enablement for semi-solid

materials. The examiner has carefully examined the specification and cannot find a recitation of this term. It is suggested that applicant use the term "viscous" or “gel-state” instead as used in original claim 35. Regarding claims 4, 46 and 47, claims dedicated to the various valves, applicant has not disclosed these valves in sufficient detail to make the subject matter enabling to one of ordinary skill in the art. No drawing is providing, and the discussion in the specification is conclusory. The mere mention of a valve is insufficient.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 22, 23, 28, 35, 40, 42, 43, 57, 58, 59, 61, 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Urquhart, US 3,797,485. See especially figures 5-9, showing an implant sealed to blood vessel 11 with adhesive. Note column

7, lines 22-44, describing the sealing and the impermeability of the outer wall 12. Membrane 20 anticipates the claimed release port. The first refilling port, although not shown, is inherent, and must comprise a cavity to be operable, even if the cavity is simply an attached syringe pump or a gravity pump from a suspended drug reservoir (IV drip). First tube is anticipated by tube 14. Note that body wall can comprise metals for reinforcement. Column 8, lines 54+. Regarding the porous barrier, see column 10, lines 3+. Regarding claim 69, the examiner notes that the solid or semisolid is not positively recited. Accordingly, even if Urquhart does not specifically mention this, the device still has "at least one mechanism for retaining a solid or semisolid" as claimed.

Claims 67, 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Theeuwes et al., US 6,726,920. Theeuwes disclose the claimed invention. Note again column 5, lines 42-47, emphasizing that the patch has "substantially no migration of the substance into or out of the patch through the impermeable layer or other impermeable portion." This reference was applied in the parent application. See also the comments set forth therein. Regarding claim 67, osmotic pumps are disclosed in column 16, line 65. Regarding claim 68, see column 5, lines 36-41, contemplating the semi-solid drugs.

Claim 69 is rejected under 35 U.S.C. 102(b) as being anticipated by Avery et al., U.S. 5,725,493. Broadly interpreted, the claims read directly over the invention. See embodiment 4, sheet 5 of Avery. Avery discloses an implantable delivery device comprising a housing 80, reservoir 110, drug release port 166, first wall 84, sealing

base for sealing the release port is anticipated by suture tabs 172, the attachment mechanism is anticipated by other suture tabs 342, and the reinforcement mechanism is anticipated by peripheral section 326 which is made of "relatively rigid, impenetrable material" which permits medial section 328 to compress as drug reservoir contents decrease without causing the entire reservoir to collapse. See column 10, lines 16-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart, '485. Applicant claims various structural elements to retain the therapeutic agent including a net. Also, see the above new matter rejection. The examiner takes the position that a net is akin to a porous membrane as an equivalent embodiment which would be functional. Regarding claim 51, it would be obvious to any of ordinary skill in the art to administer dyes, radioactive materials or any other diagnostic agent into the vein.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485 in view of Yamamoto et al., US 5,330,767. Urquhart discloses the claimed invention except for the sustained release (slow release) formulation. Yamamoto is

cited to exemplify a large body of art dedicated to sustained release fluid formulations in fluid form. It would be obvious to one of ordinary skill in the art to use a sustained release formulation with the Urquhart device to provide a sustained release of drug in the event the membrane was insufficient to control the release.

Claims 4, 5, 10, 11, 19, 47, 50, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485 in view of Finch et al., US 5,755,780. Urquhart discloses implanting the reservoir comprised of a "small plastic bag" in the host for continually supplying drug to the device. See column 15, example 6. Finch discloses the modern day refillable implant port, including the claimed valves, septum. It would be obvious to one or ordinary skill in the art to employ a modern implant port with the Urquhart device to gain the advantages thereof. Note the slit valve which prevents overfilling, fasteners 21 to secure the device to tissue.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485 in view of Jones et al., US 6,287,293. Urquhart discloses implanting the reservoir comprised of a "small plastic bag" in the host for continually supplying drug to the device. See column 15, example 6. Jones discloses the modern day refillable implant port, including the radiopaque markers to locate the septum. It would be obvious to one or ordinary skill in the art to employ a modern implant port with the Urquhart device to gain the advantages thereof, such as locating the septum.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485 in view of Olsen, US 6,152,898. Urquhart discloses implanting the reservoir comprised of a "small plastic bag" in the host for continually supplying drug to the device. See column 15, example 6. Olsen discloses the modern day refillable implant port, including the overfill protection system. See the abstract and the figures. It would be obvious to one or ordinary skill in the art to employ a modern implant port with the Urquhart device to gain the advantages thereof, such as an overfill protection system.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615